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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,777	07/22/2002	Linda A. Young	112701-339	9676
29157	7590	04/30/2004	EXAMINER	
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			SAYALA, CHHAYA D	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/070,777	Applicant(s) YOUNG ET AL.	
	Examiner C. SAYALA	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-34 is/are rejected.
- 7) ☒ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 8-24, 29 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improving the condition of an elderly pet, does not reasonably provide enablement for “reversing a sign of aging” or “increasing longevity”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Example 1 states “combining calcium with the antioxidant vitamins A and E offers a surprising and synergistic improvement”. Example 1 shows cats fed beta-carotene, vitamin E, calcium, zinc, vitamins D and K had higher values of hematocrit, hemoglobin levels and red blood cell count. The study was done over a period of 6 months. All cats were 10 years of age of presumably similar condition. An improvement in condition over a 6 month period is the basis for claiming that the animals’ longevity was increased. Example 2 shows an increase in activity over a period of a 6 month study with supplementation of the vitamins. Based on this, applicant draws an inference that the animal’s longevity has increased and that signs of aging were reversed. Furthermore, apart from an improvement in activity, and an improvement in hematocrit and hemoglobin

levels and red blood cell count, there is no other basis to make the leap of faith that supplementation of the type made in the examples for a six month period actually means increase in longevity and reversing signs of aging. The specification does not disclose what these 'signs of aging' are and there are no definitions provided.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-24, 29 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 depends from claim 23, which is to an "elderly pet" and therefore, lacks proper antecedent basis.

Claim 1 lacks proper antecedent basis because it depends from a non-existent claim 36.

In the claims, "reversal of a sign of aging" is indefinite so long as the specification does not define what these "signs" are as part of applicant's invention. It is not clear what "signs" applicant intends as part of his invention as markers of the natural process of aging. Similarly, "increasing the longevity" is of indeterminate scope because it is not clear if applicant is extending the life of a cat that is undergoing the natural process of aging or does he intend the extension of the life of a diseased cat, where diseases like cancer might be

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considered as a part of aging. The longevity of a cat is different from that of a dog and is dependent on breed and size also. The longevity of a particular breed and specie is historically established. For instance, the longevity of some breeds of cats is 15 years. A mere treatment of a disease can extend the longevity of an animal and for search purposes as well as to set out the metes and bounds of these claims, applicant must define what these terms intend to cover.

Claims 33-34 provide for the use of a pet food composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 33-34 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 7-12, 15-20, 22-25, 27, 29-30, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branam and Mosier in view of Hayek (US Patent 6310090) and Hayek et al. (US Patent 6238708) and further in view of "Keeping Current Antioxidant Vitamins in Pet Food", KC 9602, BASF, 1995.

Branam teaches the importance of calcium, zinc, vitamins including A and E, and fiber in the diet of elderly dogs. Branam teaches that calcium requirements increase moderately with age in dogs because of reduced calcium-absorptive capabilities in the small bowel. Intestinal absorption of zinc also declines with age. Increased intake of vitamins is also necessary because in older animals, changes in the digestive system and metabolism associated with aging occur. Mosier also teaches supplementing zinc and vitamin E in the diet of elderly dogs because of their observed decreased serum values. Mosier observes that increasing vitamin E appears to help older dogs regain a sense of well-being, have increased exercise tolerance and show improved hair and skin. The reference states that zinc values are decreased in older dogs. See also the last three paragraphs on page 55.

They do not teach using a vitamin precursor.

Hayek teaches that "damage caused by the accumulation of these free radicals over time causes the suppression of the immune response that occurs with age". The patent teaches the use of antioxidants in pet foods for this reason, antioxidants such as vitamin E, lutein and beta-carotene.

To incorporate a vitamin precursor such as beta-carotene instead of the vitamin itself, as taught by Branam, would have been an obvious substitution because of the benefits taught by Hayek with regard to aging. Note that the primary references already teach the vitamins A (beta-carotene being its precursor), and E, and the claims do not exclude lutein.

Hayek et al. teach the use of starches such as sorghum and oats, which would naturally contain gluten and therefore, glutamine, for older dogs to control and modulate glycemic and insulinemic responses of the older dog after a meal because it is known that with aging dogs lose glycemic control which would compromise their condition, longevity and quality of life. See col. 2.

It would have been obvious to use such sources of starch in the pet food diet of the primary references, which are supplemented as discussed above, for this advantage. As for amounts, each of the references teach the amount that can be used as supplementation for dogs or cats, with respect to each of the compounds being claimed, although some amounts are shown in units that are different from those claimed. The BASF reference, while teaching the same type of supplementation, of vitamins A and E and beta carotene, teach them in different units. Using such ranges taught by these references, it would have been obvious to find optimal amounts, depending on the specie, age and condition.

4. Claims 5, 13, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Branam and Mosier in view of Hayek (US Patent 6310090)

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and Hayek et al. (US Patent 6238708) and further in view of EP 0862863, Lowe ('Canine Nutrition', Biotechnology in Feed Industry, pages 275-287, 1988) and Shields et al. (US Patent 6156355).

The primary references are as discussed above. They do not teach the claimed subject matter of claims 5, 13, 27-28, namely, the probiotic.

EP '863 teaches that probiotic bacteria aids the inhibition of the growth and activity of pathogenic bacteria and they are useful in the treatment of conditions caused by such bacteria. The patent also teaches that the probiotic bacteria activates immune functions. See example 5; and page 5, line 56, which disclose the cell numbers of microorganism used.

Furthermore, Shields Jr et al. teach that the addition of probiotics in a diet for dogs is advantageous for gastrointestinal function. The patent states 'Microbial cultures serve as a source of enzymes to help digest food, competitively exclude harmful bacteria, and synthesize various B vitamins and antimicrobial compounds'. The patent also points out regarding glutamine that "This compound is a natural component of the body which is the primary fuel source for the intestinal cells and in particular immune cells of the gastrointestinal tract. It plays a similar role to butyric acid, provided by fiber fermentation, for health of cells of the colon. Although it may not help healthy animals at rest, it may be of benefit in stress conditions including weaning to prevent muscle breakdown as a source of this amino acid." See cols. 11 and 12, at lines 1-10. With regard to zinc, the patent states "Zinc in both inorganic and proteinate form is provided to assist in repair of intestinal cell damage. High

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levels of zinc have been used in many species with intestinal disorders with excellent results". "...glutamine and zinc ...promote intestinal cell repair". Note that all these conditions-- stress, cell repair and better gastrointestinal health, have been pointed out by the primary references, as discussed above, as requiring care in the elderly dog. Therefore, even though the Shields, Jr patent addresses these vitamins and minerals and probiotics to various breeds of dogs, and perhaps not explicitly for elderly dogs, the compounds would have the same property, effect and physiological function even in elderly dogs, and the primary references discuss the necessity of these very properties in the case of elderly dog care.

Lowe teaches that a reduced efficiency of the digestive tract occurs as a result of age and infection. See page 280. He teaches that treatment with probiotics aids states of infection with pathogenic bacteria. See page 280. The reference states that when gastrointestinal tract health is compromised, digestive efficiency is reduced and opportunistic pathogens have a rapid growth rate and this may lead to infections. The reference shows the intestinal microflora proportion in Table 3 and teaches that variations in these proportions can occur as a function of age. It would have been obvious to one of ordinary skill in the art that probiotics help the GI tract to maintain not only the health of the elderly dog but also maintain the profile of a healthy, active dog in older dogs, as taught by the EP patent and reinforced by Shields, Jr et al. and Lowe.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-21, 25-28 and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 09/856426 in view of Branam, Mosier, Hayek (US Patent 6310090) and Hayek et al. (US Patent 6238708) and further in view of "Keeping Current Antioxidant Vitamins in Pet Food", KC 9602, BASF, 1995.

The '426 application teaches increasing the activity of an elderly pet with probiotics/prebiotics. The remaining references are as discussed above. They teach that the antioxidant vitamin supplementation also increases the activity of an elderly pet and improved the quality of life. It would have been obvious to combine the claimed invention with the teachings of the reference, including the amounts taught, which encompass the values claimed herein.

This is a provisional obviousness-type double patenting rejection.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. SAYALA whose telephone number is 571-272-1405.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



C. SAYALA
Primary Examiner
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